Update on Novo Nordisk manufacturing deviation for NovoSeven©, resulting in shortages for NovoEight© and Esperoct©

Mid-June 2024, the European Haemophilia Consortium (EHC), the National Bleeding Disorder Foundation (NBDF) and the World Federation of Hemophilia (WFH) were made aware of a manufacturing deviation in the production line of several products for the treatment of haemophilia and other coagulopathies manufactured by Novo Nordisk in Denmark. This manufacturing deviation resulted in some NovoSeven (1 and 2 mg) vials being potentially underfilled in informed countries and resulted in shortages of NovoSeven, NovoEight and Esperoct.

The potential supply problems of NovoEight (a standard half-life FVIII concentrate) and Esperoct (an extended half-life FVIII concentrate), although significant, can be mitigated using several alternative standard half-life and/or extended half-life clotting factor concentrates. The EHC, NBDF and WFH expect Novo Nordisk to provide timely updates on potential shortages and the timeline of going back to normal.

NovoSeven shortages are potentially more consequential because of the limited number of alternatives and the wide spectrum of indications. NovoSeven is indicated for the treatment of bleeding episodes and for the prevention of bleeding in cases of undergoing surgery or invasive procedures for the following patient groups:

- Patients with congenital haemophilia with clotting factor VIII or IX inhibitors >5 Bethesda Units (BU)
- Patients with congenital haemophilia who are expected to have a high anamnestic response to factor VIII or factor IX administration
- Patients with acquired haemophilia
- Patients with congenital factor VII deficiency
- Patients with Glanzmann's thrombasthenia with previous or present reaction to platelet transfusions or where platelets are not readily available
- Patients with severe postpartum haemorrhage when uterotonics are insufficient to achieve haemostasis

Indications for NovoSeven are for addressing situations that can be critical and, furthermore, there are no clear alternatives to NovoSeven, except for Cevenfacta in some countries and activated prothrombin complex, i.e. FEIBA, which do not seem to have enough stock to cover some of these indications. In the case of FEIBA, it is indicated following a very strict regimen in the case of haemophilia A patients with inhibitors using emicizumab.

The manufacturing issue has not caused intermittent supply problems for the time being, but its full impact might manifest later, likely by the end of 2024.

The EHC and WFH have communicated with their national member organisations (NMOs) and will keep informing them of any relevant information provided by Novo Nordisk. Haemophilia treatment centres (HTCs) and regulators around the world are aware of the situation.

The EHC, NBDF and WFH have stayed in touch with Novo Nordisk and are expecting more details on the stocks under quarantine, the number of vials that could potentially be shipped and used and on the timeline to go back to normal for all three drugs.

In the meantime, the EHC, NBDF and WFH recommend patients using NovoSeven, NovoEight and Esperoct, to contact their healthcare providers and seek advice.